REMARKS

Applicants respectfully request reconsideration of the present application in view of the foregoing amendments and in view of the reasons which follow.

Introduction

Upon entry of the amendment set forth above, claims 1-47 are pending in the present application. Applicants acknowledge that claims 1-15 are subject to the examination and that all of the non-elected claims may be rejoined upon the indication of allowable subject matter within the scope of the allowable subject matter.

Applicants have revised claims 3 and 10 to define the claimed invention more clearly by reciting "extracellular polysaccharide." Support of the amendment is found throughout the specification, for example, paragraphs 245 and 253. Applicants have also added claims 46 and 47 to define further that the microorganism contained in the claimed pharmaceutical composition is capable of converting an oligosaccharide into a polysaccharide. Support for the new claims can be found throughout the specification, for example, paragraphs 33 and 35.

Applicants also have revised the specification to provide the address of the Korean depository.

I. Rejection of Claims 1, 3-7 and 10-14 under 35 USC § 102(b) or § 103(a)

The examiner has rejected these claims on grounds of alleged anticipation by or, in the alternative, obviousness over Sawada *et al.* ("Sawada"). The examiner contends that Sawada teaches a pharmaceutical containing an effective amount of microorganism capable of producing polysaccharide, or in the alternative, one skilled in the art would have been motivated from the teachings of Sawada to isolate *Lactobacillus sp.* and to use such a microorganism in a pharmaceutical. Applicants respectfully traverse the rejection.

Sawada teaches antihypertensives containing "polysaccharide-peptidoglycan complexes" that are the cell wall component of Gram-positive bacteria. Sawada further teaches that, in a preferred embodiment, the complexes used in the pharmaceutical are derived from lactic acid bacteria such as *Lactobacillus* or *bifidobacterium*. Because Sawada uses the complex and not the bacteria, the reference actually describes how to

isolate the complexes from bacteria and to purify them to use in a pharmaceutical composition. Thus, the teachings of Sawada are limited to a pharmaceutical comprising the polysaccharide complexes isolated from such bacteria. In other words, the pharmaceutical composition disclosed in Sawada comprises no bacteria of any sort, let alone bacteria that produce an extracelluar polysaccharide. Contrary to the examiner's assertion, Sawada nowhere even implicates the use of such bacteria *per se* as pharmaceutical agents.

As for the rejection of claim 1, Sawada does not teach the specific strain of *Lactobacillus,* BC-Y009, claimed in claim 1. As substantiated in the working example, BC-Y009 converts an oligosaccharide into a polysaccharide under the conditions of simulated intestine to produce an extracellular polysaccharide. There is no teaching that any of the bacteria described in Sawada can convert an oligosaccharide into a polysaccharide to produce an extracellular polysaccharide, as the claimed strain, BC-Y009, does. Therefore, the recited strain, BC-Y009, is clearly differentiated from the bacteria described in Sawada.

It is axiomatic that an anticipating reference must describe each element of the claimed invention. Because Sawada teaches neither the recited *Lactobacillus* strain nor a pharmaceutical composition comprising bacteria *per se*, the publication does not qualify as an anticipatory reference.

Neglecting such deficiencies of Sawada, the examiner further contends that one skilled in the art would have been motivated to isolate *Lactobacillus sp.* and to use such a microorganism in a pharmaceutical because Sawada teaches all these features. As applicants explained above, what Sawada teaches is the use of the complex obtained from bacteria in pharmaceuticals, but the use of bacteria themselves as a pharmaceutical. Therefore, Sawada fails to evidence any motivation for one of ordinary skill in the art to use a microorganism that is capable of producing an extracellular polysaccharide in a pharmaceutical composition as claimed invention. Accordingly, there is no *prima facie* case of obviousness established in this case.

II. Rejection of Claims 1-15 under 35 USC § 103(a)

The examiner also has rejected claims over Sawada in view of Becker *et al.* ("Becker") and, if necessary, in further view of Toyosaki *et al.*("Toyosaki"). Applicants respectfully traverse the rejection.

In the preceding section, applicants identified the deficiencies of Sawada. Neither Becker nor Toyosaki cures such deficiencies.

As noted by the examiner, Becker's teachings also are limited to a pharmaceutical composition comprised of dietary fiber that includes polysaccharides. Furthermore, the polysaccharides described in Becker are derived from either the plant cell-wall or cell content. Becker, however, does not hint at using a microorganism that is capable of producing an extracelluar polysaccharide in the pharmaceutical composition disclosed therein. Accordingly, Becker does not provide any motivation for one of ordinary skill in the art to use a microorganism described in Sawada in a pharmaceutical, as in the claimed invention. Even if there were such a motivation, furthermore, the fact remains that the microorganism described in Sawada does not produce an extracellular polysaccharide; hence, no reasonable combination of Becker with Sawada leads to the claimed invention.

Toyosaki allegedly teaches *Acetobacter* strain capable of producing a polysaccharide. Toyosaki observes cellulose accumulation by *Acetobacter* strains in culture media and reports *Acetobacter* sp. BPR 2001 as a producer that yielded the highest cellulose accumulation. The strain BPR 2001 is isolated from a black cherry. (See first full paragraph, right column, at page 1500). In addition, Toyosaki states that isolation from fruits is particularly efficient as a cellulose producer. (See abstract and second full paragraph, left column, at page 1501.)

By contrast, the *Acetobacter* sp. BC-Y058 of the instant application is isolated from glucose factory sewage and is verified as a new strain. (See paragraph 0246 and example 1.) In view of Toyosaki suggesting *Acetobacter* sp. isolated from fruits as a particularly efficient cellulose producer, one of ordinary skill in the art would not have been motivated to isolate *Acetobacter* strain from factory sewage.

Further, while Toyosaki teaches the use of this strain to produce cellulose in a jar fermentor, there is no suggestion that this strain could be used in a pharmaceutical composition, as presently recited. Alone or in combination with other prior art, therefore, no reasonable reading of Toyosaki could have motivated one skilled in the art to have employed this *Acetobacter* strain in a pharmaceutical composition.

In conclusion, because none of the cited prior art teaches or suggests the use of a microorganism that is capable of producing an extracellular polysaccharide as a

pharmaceutical, the cited prior art, alone or in combination, evidences no motivation for one of ordinary skill in the art to modify their teachings to produce a pharmaceutical composition comprising a microorganism recited in the claims. Therefore, there is no *prima facie* case of obviousness established. Accordingly, applicants respectfully request reconsideration and withdrawal of all of the claims rejections.

With respect to new claims 45 and 47, applicants note that these claims prescribe that the microorganism is capable of converting oligosaccharide into polysaccharide. Besides the lack of disclosure of using a microorganism as pharmaceuticals, none of the cited prior art teaches or implicates that the disclosed microorganism can convert oligosaccharide into polysaccharide. Thus, applicants submit that the current rejections are not applicable to new claims 46 and 47.

In view of the foregoing, applicants request favorable reconsideration and allowance of the pending claims. If there are any issues remaining which the examiner believes could be resolved through either a supplemental response or an examiner's amendment, the examiner is invited to contact the undersigned at the telephone number listed below.

Respectfully submitted,

Date 19 March 2003 By S. G. Bent

FOLEY & LARDNER
Washington Harbour
3000 K Street, N.W., Suite 500
Washington, D.C. 20007-5109
Telephone: (202) 672-5404
Facsimile: (202) 672-5399

Stephen A. Bent
Attorney for Applicants
Registration No. 29,768

MARKED-UP COPY

In the Specification

At page 32, please substitute the paragraph 270 with the following:

-- Upon consideration of the result of analysis of phenotype and 16s rRNA DNA sequence, BC-Y009 was named as *Lactobacillus* sp. BC-Y009 and BC-Y058 as *Acetobacter* sp. BC-Y058. They were deposited in KCTC(Korean Collection for Type Cultures, located at Korea Research Institute of Bioscience and Biotechnology (KRIBB), #52, Oun-dong, Yusong-ku, Taejon, 305-333, Republic of Korea) on May 30, 2000, and the deposit number were granted as KCTC BC-Y009, KCTC BC-Y058, respectively.—

In the Claims

3. (Amended) A pharmaceutical composition comprising at least one microorganism selected from the group consisting of *Acetobacter* sp., *Leuconostoc* sp., *Bacillus* sp., *Lactobacillus* sp., *Streptococcus* sp., *Bifidobacterium* sp., *Lactococcus* sp. and *Pediococcus* sp. bacteria in an amount effective to prevent or treat obesity and a pharmaceutically acceptable carrier, wherein the microorganism is capable of producing an extracellular polysaccharide.

10. (Twice Amended) A pharmaceutical composition comprising at least one microorganism selected from the group consisting of *Acetobacter* sp., *Leuconostoc* sp., *Bacillus* sp., *Lactobacillus* BC-Y009, *Lactobacillus brevis, Lactobacillus helveticus, Lactobacillus bulgaricus, Lactobacillus casei, Lactobacillus kefir, Lactobacillus keriranofaciens, Lactobacillus bifidus, Lactobacillus sake, Lactobacillus reuteri, Lactobacillus lactis, Lactobacillus delbrueckii, Lactobacillus helveticusglucos var. jugurti., Streptococcus* sp., *Bifidobacterium* sp., *Lactococcus* sp. and *Pediococcus* sp. bacteria in an amount effective to prevent or treat diabetes mellitus and a pharmaceutically acceptable carrier, wherein the microorganism is capable of producing an extracellular polysaccharide.